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K031782

GAPP™ Graft Containment Device
510(k) Summary
June 2003

I. **Company:** **Medtronic Sofamor Danek**
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133

II. **Proprietary Trade Name: GAPP™ Graft Containment Device**

III. **Regulation Number: 888.3060 - KWQ**

IV. **Product Description**

The GAPP™ Graft Containment Device consists of bone fixation devices used in spinal fusion procedures. The graft containment device is available in a wide range of sizes for use in maintaining the relative position of weak bony tissue such as bone grafts. The graft containment device implants maintain the stability of weak bony tissue during the healing period.

V. **Indications**

Properly used in conjunction with traditional rigid fixation, this system is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing indications.

VI. **Substantial Equivalence**

Documentation was provided which demonstrated the GAPP™ Graft Containment Device to be substantially equivalent to the MacroPore OS Implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 1 2005

Mr. Richard Treharne, Ph.D.
Senior Vice President Regulatory Affairs
Medtronic Sofamor Danek, Inc.
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K031782
Trade/Device Name: GAPP™ Graft Containment Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: December 1, 2004
Received: December 2, 2004

Dear Dr. Treharne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

for Celia M. Witten,Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031782

Device Name: GAPP™ Graft Containment Device

Indications for Use:

Properly used in conjunction with traditional rigid fixation, this system is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. This device is not intended for load bearing indications.

Prescription Use ____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhauser

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K031782